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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,008

Applicant(s)

CADY, ROGER

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 14, 15, 17-21, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/15/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 14-24 are pending.

Applicants' amendment filed on May 19, 2005 is acknowledged. Applicants' response has been fully considered. Claims 1-13 have been cancelled, claims 14-16 have been amended, and new claims 17-24 have been added. Thus, claims 14-24 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-9 and 16 under 35 U.S.C. 112, second paragraph, regarding effective amount and antecedent base, is withdrawn in view of applicant's cancellation of the claims, and applicants response at pages 6-7 in the amendment filed May 19, 2005.

Withdrawn Claim Rejections - 35 USC § 102

3. The previous rejection of claims 1-3, 5-7 and 9 under 35 U.S.C. 102(e), as being anticipated by Donovan (US 2004/0009180), is withdrawn in view of applicant's cancellation of the claims in the amendment filed May 19, 2005.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Previous rejection of claims 14-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained, and claim 19 has been added. Applicant's arguments have been fully considered, and the response to the argument is shown below.

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5. Claim 14 and 15 are indefinite because of the use of the term “the sensory neuron related disorder” or “disorders associated with the release of neurotransmitters in trigeminal neurons”.

The term cited renders the claim indefinite, it is unclear what diseases “the sensory neuron related disorder” or “disorders associated with the release of neurotransmitters in trigeminal neurons” refers to besides migraine and diabetic neuropathy since the specification does not identify various diseases related to the sensory neuron except for migraine.

Response to Arguments

Applicants indicate the term “sensory neuron related disorder” was sufficiently described throughout the specification as those disorders that caused by or are associated with the release of neurotransmitters from sensory neurons, and the specification has provided two specific examples of such disorders: migraine and diabetic neuropathy (page 7 of the response).

Applicants’ response has been considered, however, the argument is not found persuasive because the specification only cites the term “migraine and other sensory neuron related disorders” (see paragraphs [0002], [0010]-[0014], [0019]), it does not identify other sensory neuron related disorders except for migraine.

6. Claim 19 recites the limitation “the neuropeptide” in line 2. There is insufficient antecedent basis for this limitation in the claim.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Previous rejection of claims 14 and 15 under 35 U.S.C. 102(e) as being anticipated by Donovan (US 2004/0009180, filed July 11, 2002) is maintained, and new claims 18-21, 23 and 24 have been added. Applicant's arguments have been fully considered, and the response to the argument is shown below.

Donovan teaches a pharmaceutical composition containing a botulinum toxin (e.g., botulinum toxin type A) is used to treat several types of disorders associated with neurotransmitter release (e.g., migraine, fibromyalgia, pain from muscle spasm) by topical administration of effective amount of the composition (paragraphs [0043], [0066]; Examples 3, 4 and 6; claims 18 and 20), wherein the botulinum toxin can be lyophilized, reconstituted with saline or water, and an enhancing agent such as alcohol or lipid can be added to the composition (paragraphs [0069]-[0073]; claim 21); the composition containing the botulinum toxin and the enhancing agent is provided in a transdermal patch having an adhesive layer, a reservoir holding the botulinum toxin and an exterior surface (paragraphs [0074]-[0075]; claims 23, 24). The reference also indicates the botulinum toxin may act on the sensory neurons to decrease the release of substance P or CGRP (calcitonin gene-related peptide) to reduce inflammation and pain associated with inflammation (paragraph [0085]; claims 14, 15 and 19). Although the

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reference does not specifically recites the use of botulinum toxin to inhibit the release of transmitters in trigeminal neurons, it teaches topically administering botulinum toxin, which acts on sensory neurons to inhibit the release of CGRP (paragraph [0085]), in the treatment of migraine, which has the same method steps as the claimed method, thus meets the criteria of the claimed invention.

Response to Arguments

Applicants indicate the Examiner appears to acknowledge that Donovan does not refer to the inhibition of neuropeptides such as calcitonin gene-related peptide or the specific inhibition of neurotransmitters in trigeminal neurons, and Donovan's non-specific reference to treatment of disorders associated with neurotransmitter release is not suggestive of the inhibition of trigeminal-associated neuropeptides (page 8 of the response).

Applicants' response has been considered, however, the argument is not found persuasive because Donovan teaches topically administering an effective amount of botulinum toxin in the treatment of migraine, which has the same method steps as the claimed method (transdermally applying a pharmaceutically effective amount of botulinum toxin A to an affected area of a human exhibiting symptoms of migraine, claim 18), thus meets the criteria of the claimed invention. The reference also indicates the possible mechanism is that botulinum toxin acts on sensory neurons to inhibit the release of CGRP (paragraph [0085]).

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan (US 2004/0009180) in view of Ho *et al.* (U.S. Patent 5, 770, 567 published June 23, 1998).

Donovan teaches a pharmaceutical composition containing a botulinum toxin (e.g., botulinum toxin type A) is used to treat several types of disorders associated with neurotransmitter release (e.g., migraine, fibromyalgia, neurogenic inflammation) by topical administration of effective amount of the composition (paragraphs [0043], [0066]), where the composition can deliver the botulinum toxin to a subdermal sensory neuron (paragraphs [0044]); and the botulinum toxin may act on the sensory neurons to decrease the release of substance P or CGRP (calcitonin gene-related peptide) to reduce inflammation and pain associated with inflammation (paragraph [0085]). However, Donovan does not specifically disclose the use of botulinum toxin type A for the treatment of diabetic neuropathy.

Ho *et al.* disclose diabetic neuropathy is one example of the diseases involving the sensory neurons (column 38, lines 15-19).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art is motivated to use botulinum toxin A for the treatment of a sensory neuron related disorder as taught by Donovan to treat diabetic neuropathy as taught by Ho *et al.* because topical administration of botulinum toxin A can deliver the botulinum toxin to subdermal sensory neuron and inhibit the release of substance P or CGRP to reduce inflammation and pain associated with inflammation, thus to treat a sensory neuron related disorder such as diabetic neuropathy. Therefore, the combined references result in the claimed invention and was, as a whole, *prima facie* obvious at the time the claimed invention was made.

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8. Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Claims 14-15, 17-21, 23 and 24 are rejected; and claim 22 is objected to. It appears that claim 16 is free of art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

July 13, 2005